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EXAMINER	
CARTER, KENDRA D	

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1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,069	CAWTHON, GARRET D.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-53,57,60,74-76 and 87-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-53,57,60,74-76 and 87-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of January 21, 2009 made to the office action filed September 17, 2008. Claims 39-53,57,60,74-76 and 87-95 are pending. Claim 95 is new.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 39, 40, 44-50, 52, 53, 57, 74-76 and 87 as being unpatentable over Paul et al. in view of Goldberg et al. and in further view of Heilig were found persuasive, and thus withdrawn. Particularly, the disclosure relied upon in the Paul et al. reference is not supported in the provisional application in which it receives its priority. Thus, Paul et al. reference does not qualify as prior art and is therefore withdrawn. Therefore, all further 35 U.S.C. 103(a) rejections are also withdrawn.

Due to the Applicant's arguments being persuasive the new 103(a) rejections are made below. The Applicant's arguments of the previous 35 U.S.C. 112, first paragraph rejection of claim 39 is not being persuasive, thus the rejection is upheld and repeated below. Since there are new rejections that are not due to amendments to the claims, a new Non-Final Office Action is made below and Applicant's arguments are not addressed on cancelled rejections. The Applicant's arguments regarding the 35 U.S.C. 112, first paragraph rejection is addressed below.

Claim Objections

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Particularly, claim 49 does not further limit the composition of claim 39 because it requires a fluid base material which is already required in the composition of claim 39.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid particulate material selected from the group zinc oxide, talc, calamine or kaolin, does not reasonably provide enablement for all solid particulate material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of treating diaper rash comprising a composition including a fluid base material and a solid particulate material. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 39 is drawn to "a method for treating diaper rash ....wherein the composition includes: (1) a fluid base material comprising a member selected from the group consisting of mineral oil, silicone oil, an organic solvent, plant-based oil, water and mixtures thereof, and (2) a solid particulate material."

(2) The breadth of the claims:

Claim 39 embraces treating diaper rash with any solid particulate material. This The specification does not enable the treatment of diaper rash with any solid particulate material.

(3) The state of the prior art:

The state of the art regarding treating diaper rash with any solid particulate material is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability treating diaper rash with any solid particulate material is relatively low. Therefore, to one skilled in the art, treating diaper rash with any solid particulate material is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high. Melloh et al. (US 4,307,089) teaches that the solid particulate, sodium pyrithione irritates skin in 40 and 48% solutions (see column 1, line 44-48). Thus, all solid particulates are not useful to treat diaper rash because they can irritate the skin.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treatment of diaper rash with any solid particulate material is completely lacking. The specification teaches

that the composition comprises at least about 1% solid particulate material, in which zinc oxide is preferred (see page 14, second paragraph). Zinc oxide can be substituted or combined with other solids such as talc, calamine or kaolin (see page 17, lines 3-5). The specification as filed does not speak on or show any working examples any studies performed that demonstrate that any solid particulate material can treat diaper rash. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on treating diaper rash with any solid particulate material. As discussed above the specification fails to provide any support for treating diaper rash with any solid particulate material. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating diaper rash with a solid particulate material selected from the group zinc oxide, talc, calamine or kaolin, but not for any solid particulate material.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2) Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, claim 49 does not further limit the composition of claim 39 because it requires a fluid base material which is already required in the composition of claim 39. Further, the Examiner does not know if the composition further comprises all of the components of claim 49 or that the fluid base material is selected from one of the components in claim 49. Claim 50 is not clear because it is dependent on claim 49, which is not clear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 39, 40-45, 46-48, 51-53, 57, 60, 76 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fourman et al. (US 4,963,591) in view of Goldberg et al. (US 5,176,903), Heilig (US 3,079,299), and Clark et al. (US 6,103,245).

Fourman et al. teach a diaper rash treatment composition comprising alcohol, panthenol, beeswax, cod liver oil, talc, lanolin, mineral oil, calamine, cade oil, corn starch, glycerin, starch, iron oxide, and silicone (see columns 5-7, diaper rash lotion; addresses claims 39, 44, 46, 48, 51-53, 57, 60, 76 and 95). The compositions provide thin, substantive, flexible films which do not crack, peel or crack; which are water-proof and do not have an oily greasy sticky or waxy feel and which provide good, long-term adhesion for cosmetically active material to the skin (see column 1, lines 12-20; addresses claims 39 and 95). The amount of active material varies depending upon the particular actives selected and the results desired. The amount of solvent is from about 10% to about 90% (see column 2, lines 30-36 and 59-64; addresses claim 47). A volatile silicone fluid can be employed as an emollient, such as cyclomethicone (see column 3, lines 23, 24 and 29; addresses claims 44 and 45).

Fourman et al. do not teach zinc oxide (claims 40 and 95) or the particle size of zinc oxide (claims 41-43 and 60). Fourman et al. also does not teach that the

composition is suitable to be sprayed (claims 39 and 95), or that specific ranges of zinc oxide and the fluid base material (claim 47).

Goldberg et al. teaches an antiperspirant/deodorant composition which may be in the form of a pump spray, cream or lotion (see column 2, lines 1-6). The lotions are liquid based with suitable liquids such as silicones, glycols and emollients (see column 2, lines 15-17). Silicones include dimethicone and cyclomethicone, which provides a pleasant layer on the skin which enhances feel (see column 4, lines 42-49). The composition also comprises absorbants such as talc, starch and zinc oxide (see column 5, lines 25-31). The composition can also comprise a drying enhancer that enables the composition to dry more quickly such as isopropyl alcohol or ethanol (see column 6, lines 4-7).

Heilig teaches a self-propelling medicinal ointment composition and method of application to treat diaper rash, by rapidly releasing the medicament in the form of a spray or mist to the part of the body to be treated (see title and column 1, lines 11-16, 30-36 and see column 5, lines 42-45).

Clark et al. teaches a composition for superior, longer-lasting barrier formulation as a protective barrier for incontinent patients along with managing diaper rash in humans (see column 4, lines 55-59). The inorganic barrier component zinc oxide is

used and should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Zinc oxide has a mild astringent, protective and antiseptic action. Thus it is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Fourman et al. and wherein the solid material is zinc oxide (claims 46, 48 and 95) and the particle sizes disclosed in claims 41-43 and 60) because of the following teachings: 1) Fourman et al. teach a diaper rash treatment composition that comprises talc and starch (see columns 6 and 7, diaper rash lotion); 2) Goldberg et al. teach diaper rash compositions that comprise absorbants such as talc, starch and zinc oxide (see column 5, lines 25-31); 3) Clark et al. teach that in long lasting barrier formulations for diaper rash zinc oxide is used as a mild astringent, protective and antiseptic action, and is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14); and 4) Clark et al. also teach that zinc oxide should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Thus, one would be motivated to use zinc oxide in the particle size disclosed in claims 41-43 and 60 because it is has several desirable properties in diaper rash formulations. One skilled in the art would be able to determine the optimal particle size

of zinc oxide by routine experimentation. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Fourman et al. and wherein the composition is in a spray because of the following teachings: 1) Heilig et al. teaches that by spraying the composition directly on the treated area, the diaper rash treatment is released rapidly (see title and column 1, lines 11-16, 30-36 and see column 5, lines 42-45); and 2) Goldberg et al. teaches a composition comprising similar components as the Applicant and Fourman et al., such as a silicone oil and a solid particulate material, can be formulated into a pump spray (see column 2, lines 1-6; see column 4, lines 42-49; and see column 5, lines 25-31). Thus, the composition of Fourman et al. would provide a protective barrier on the skin faster if applied by a spray directly to the effected area then by transfer from the diaper. In regards to the spray being atomized, Goldberg et al. has demonstrated that the Applicant's composition can be sprayed in a pump spray.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Fourman et al. and the specific ranges of zinc oxide and the fluid base material (claim 47) because Fourman et al. teach that

the amount of active material varies depending upon the particular actives selected and the results desired, and the amount of solvent is from about 10% to about 90% (see column 2, lines 30-36 and 59-64). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(2) Claims 39, 40, 44-48, 57, 74-76, 87 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,652,274) in view of Goldberg et al. (US 5,176,903).

Martin teaches a therapeutic wound healing compositions and methods for treating diaper rash (see column 40, lines 27 and 28; addresses claims 39 and 95; i.e. a skin treatment area normally covered by a diaper and treating diaper rash). The compositions comprise water and/or water-miscible organic solvents (see column 38, lines 16-17 and column 43, lines 33-41; addresses claims 39 and 95), but a wide variety of pharmaceutical acceptable carriers may be used (see column 144, lines 16-23). The compositions can be prepared into a spray for topical delivery (see column 43, lines 29-23). The composition may also contain conventional additives employed in these type products such as humectants, emollients, lubricants, stabilizers, dyes and perfumes (see column 43, lines 43-48; addresses claim 57). The composition comprises solid particulate material such as pyruvate salts (see claim 1) and antiseptic agents such as

zinc oxide (see column 141, lines 4-5; addresses claims 39, 40 and 95). The composition is coated on the skin treatment area (see column 102, lines 52-54; addresses claims 39 and 95; i.e. leaving the composition on the skin treatment area to form a coating). The healing composition is from about 0.1% to about 10% and the topical vehicle is in an amount sufficient to bring the total amount of composition to 100% by weight (see column 44, lines 14-25).

Martin does not teach that the composition is sprayed from an atomizing spray dispenser (claims 39 and 95), particularly a pump spray (claims 74, 75 and 87). Martin also does not specifically teach wherein the fluid composition has a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser (claims 39 and 95). Martin also does not teach wherein the fluid base material comprises a volatile compound that evaporates after passage through the atomizing spray dispenser (claim 76). Martin also does not teach a fluid base material selected from the group consisting of mineral oil, silicone oil, plant-based oil (claims 44 and 45), or that the composition further comprises talc, paraffin Wax, or microcrystalline wax (claim 46). Martin also does not teach wherein the solid material is selected from the group consisting of talc, calamine and kaolin (claim 48). Lastly, Martin does not teach the amount of zinc oxide and the fluid base material as disclosed in claim 47.

Goldberg et al. teaches an antiperspirant/deodorant composition which may be in the form of a pump pray, cream or lotion (see column 2, lines 1-6). The lotions are

liquid based with suitable liquids such as silicones, glycols and emollients (see column 2, lines 15-17). Silicones include dimethicone and cyclomethicone, which provides a pleasant layer on the skin which enhances feel (see column 4, lines 42-49). The composition also comprises absorbants such as talc, starch and zinc oxide (see column 5, lines 25-31). The composition can also comprise a drying enhancer that enables the composition to dry more quickly such as isopropyl alcohol or ethanol (see column 6, lines 4-7).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Martin and wherein the fluid base material is a silicone oil (claims 44 and 45), or wherein the solid material is talc (claims 46 and 48) because of the following teachings: 1) Martin teaches that the composition may also contain conventional additives employed in the art such as humectants, emollients, lubricants, stabilizers, dyes and perfumes (see column 43, lines 43-48); and 2) Goldberg et al. teach that silicones including dimethicone and cyclomethicone, provides a pleasant layer on the skin which enhances feel (see column 4, lines 42-49), and absorbants are those such as talc, starch and zinc oxide (see column 5, lines 25-31). Thus, one would be motivated to use silicones to provide a pleasant layer on the skin which enhances feel. Further one would be motivated to use talc because it is an absorbent like zinc oxide, which is used in the composition of Martin (see column 141, lines 4-5).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Martin and wherein the composition is sprayed on the skin treatment area to provide a moisture barrier over the skin from an atomizing spray dispenser (claim 39), particularly a pump spray (claims 74, 75 and 87) because of the following teachings: 1) Martin teaches the Applicant's diaper rash composition that can be sprayed on the diaper rash such at the treatment area is coated with the composition (see column 40, lines 27 and 28; column 43, lines 29-23; and column 102, lines 52-54); and 2) Goldberg et al. teaches a composition comprising similar components as the Applicant, such as a silicone oil and a solid particulate material, can be formulated into a pump spray (see column 2, lines 1-6; see column 4, lines 42-49; and see column 5, lines 25-31). Thus, Martin and Goldberg et al. has demonstrated that the Applicant's composition can be sprayed, in which Goldberg et al. teaches the pump spray. In regards to the moisture barrier obtained over the skin, Martin teaches the Applicant's composition. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Martin and wherein the composition comprises a volatile compound that evaporates after passage through the atomizing spray dispenser (claim 76) because of the following teaching: 1) Goldberg et al. teaches that a drying enhancer such as ethanol (i.e. a volatile compound) enables the composition to dry more quickly (see column 6, lines 4-7). One skilled in the art would further apply a drying enhancing agent such that the composition would be immediately effective upon leaving the pump spray.

In regards to wherein the fluid composition has a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser (claims 39 and 95), Martin and Goldberg et al. has demonstrated that the Applicant's composition can be sprayed, thus the limitation is obviously met.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Martin in view of Goldberg et al. and the specific ranges of zinc oxide and the fluid base material (claim 47) because Martin teaches that the healing composition is from about 0.1% to about 10% and the topical vehicle is in an amount sufficient to bring the total amount of composition to 100% by weight (see column 44, lines 14-25). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(3) Claims 41-43 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,652,274) in view of Goldberg et al. (US 5,176,903) as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above, in further view of Clark et al. (US 6,103,245).

The teachings of Martin and Goldberg et al., are as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above.

Martin and Goldberg et al. does not teach the average particle size of zinc oxide (claims 41-43 and 60).

Clark et al. teaches a composition for superior, longer-lasting barrier formulation as a protective barrier for incontinent patients along with managing diaper rash in humans (see column 4, lines 55-59). The inorganic barrier component zinc oxide is used and should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). Zinc oxide has a mild

astringent, protective and antiseptic action. Thus it is often used in the treatment of skin disorders and a number of epidermal infections (see column 7, lines 11-14).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Martin in view of Goldberg et al., and the average particle size of zinc oxide as disclosed in claims 41-43 and 60 because Clark et al. teaches that zinc oxide should be micronized to a particle size such that the barrier composition itself, after the addition of the inorganic component, is a smooth homogeneous composition that is essentially grit free (see column 7, lines 5-9 and claim 20). One skilled in the art would be able to determine the optimal particle size of zinc oxide by routine experimentation.

(4) Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above, in further view of Steuart et al. (US 5,330,756).

The teachings of Paul et al. and Goldberg et al. are as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above.

Paul et al. and Goldberg et al. do not teach calendula extract, chamomile extract, comfrey extract, or a plant based oil.

Steuart et al. teaches a method of treating a variety of skin conditions, such as diaper rash (see column 6, lines 19 and 20) with a therapeutic formulation comprising concentrated fluid plant extracts such as *S. officinale* (see abstract, lines 4, 5, and 11-14; column 4, line 45; and column 5, lines 29-32), and olive oil, castor oil, and jojoba oil (i.e. plant based oils; see column 10, example B2 and B3). Alcohol or glycol extract solutions of *S. officinale*, which is called "comfrey" has been recognized for decades for its healing properties, particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64). The formulations are formulated into a spray (see column 5, lines 50-53). In oil and water emulsion formulations, the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. and Goldberg et al., and comfrey extract and a plant based oil because Steuart et al. teaches a method of treating diaper rash with and comfrey extract in a variety of plant based oils. The benefit of using comfrey extra in an oil is because of the following teachings by Steuart et al.: (1) comfrey extracts have been recognized for decades for its healing properties,

particularly for its ability to stimulate epithelial development externally in the case of skin damage (see column 1, lines 21, 21, and 61-64); and (2) the oil is the dispersed phase for the purpose of protecting, moisturizing, and stimulating the healing processes of skin or mucous membrane (see column 5, lines 40-44). Additionally, since the composition can be formulated into a spray, the above ingredients can be used in the method of Paul et al. and Goldberg et al.,

(5) Claims 74, 75, 87, 89, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above, in further view of Ando (US 5,881,925).

The teachings of Paul et al. and Goldberg et al. are as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above.

Paul et al. and Goldberg et al. do not teach a pump spray dispenser and a pressure release device (claims 74, 75 and 87). A piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston is also not taught (claim 89). Lastly, a manually actuated or reciprocating actuator spray delivery mechanism is not taught (claims 93 and 94).

Ando teaches a atomizer of the reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64; addresses claims 74, 75, 87, 89 and 94). Conventionally, atomizers that spray a mixture of liquid and powder are available such that the user shakes the mixture well in the container and then the push button is pressed. The atomizing tube is pushed in and opens the valve and the mixture is atomized through the nozzle (see column 1, lines 13, 14, and 18-23; addresses claim 93). The reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Heilig and a reciprocating pump type device with a piston-style dispenser, wherein pressure is maintained on the composition by pressure of the piston because Ando teaches the following: (1) reciprocating pump type with a push button that is capable of being pressed with a finger, a piston which is pushed down by pressing the push button, a pressure chamber formed with the cylinder and the piston that has an inlet leading to the inside of the container and an outlet

leading to the internal passage in the push button, the outlet of the pressure chamber moves against the force increased when the piston is pressed by the push button to open the above outlet (see column 1, lines 46 and 52-64); and (2) the reciprocating pump type device provides an atomizer that is capable of stirring a mixture sufficiently and atomizing both powder and a liquid when used (see column 1, lines 24-32). Being that the applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. and Goldberg et al., and a spray delivery comprising a manually actuated spray delivery mechanism is because as taught by Ando, it is the conventional way to atomize liquid and solid compositions (see column 1, lines 13, 14, and 18-23). Being that Paul et al., Goldberg et al. and Applicant's method comprises a liquid and solid, this device would be suitable to deliver the diaper rash composition.

(6) Claims 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above, in further view of Davies et al. (US 5,169,037).

The teachings of Paul et al. and Goldberg et al. are as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above.

Paul et al. and Goldberg et al. do not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag (claims 90 and 91).

Davies et al. teaches a product dispenser with a product bag. Pressure in the container surrounding the bag determines the dispensing pressure (see abstract, lines 1-4; addresses claims 90 and 91). The product bag is constructed of a suitable barrier material, which may take the form of a gas impervious material (see column 2, lines 6-8 and 31-33) and the height should be approximately equal to the different between the in inside can height (see column 7, line 51 and 52). The pressure regulating system is configured so as to permit product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. and Goldberg et al., and a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can or wherein the pressure is maintained upon the composition by a pressurizing gas received in the can and externally to the bag because Davies et al. teaches the above bag-in-can style dispenser, which permits product dispensing with an unrestricted orientation of the product dispenser while avoiding loss in product dispensing pressure or interruption of product dispensing (see column 2, lines 59-64). Additionally, the product has the following advantages: (1) the capability of choosing a starting pressure depending upon the amount of product fill in the product bag together with a given can size and product bag size; and (2) off the shelf actuators which are cheaper and less prone to clogging than special units designed for wide range of pressure in the dispensing of the product can be used (see column 14, lines 36-45).

(7) Claims 90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (US 6,217,890 B1) in view of Goldberg et al. (US 5,176,903), as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above, in further view of Hanson et al. (US 5,249,747).

The teachings of Paul et al. and Goldberg et al. are as applied to claims 39, 40, 44-48, 57, 74-76, 87 and 95 above.

Paul et al. and Goldberg et al. do not teach a bag-in-can-style dispenser, wherein the pressurized compartment is a polymeric bag received inside a rigid can. Also, an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state is not taught.

Hanson et al. teaches a dispensing system for viscous fluids having a viscosity of greater than 60 cps (see column 3, lines 44-48), particularly vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Paul et al. in view of Goldberg et al., and the specific bag-in-can-style dispenser, bladder pack container (Applicant refers to an elastic shape-memory bag wherein the pressure is maintained upon the composition by maintaining the bag in an expanded state as a bladder pack container on page 25, paragraph 1, lines 6-8) because Hanson et al. teaches a dispensing system for viscous vegetable oil containing compositions in closed pressurized containers such as bladder packs (see column 2, lines 8-13). Being that Paul et al. teaches a composition comprising a viscosity enhancer, which helps stabilize the formulation on the surface

(see column 15, lines 6-9), this device would be suitable to deliver the diaper rash composition.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant argues that there is no limitation in claim 39 requiring that the solid particulate material have a therapeutic effect, produce any particular result or effect on the patient's skin, or have any particular function on the skin treatment area, and the only function of the diaper rash treatment composition as a whole recited in claim 39 is to "provide a moisture barrier over the skin treatment area." Further Melloh et al. indicates that sodium pyrithione is a skin irritant in highly concentrated solutions, which is not a solid particulate material as claimed in claim 39.

The Examiner disagrees because the Applicant's formulation is fluid. Also, regardless if the sodium pyrithione is dissolved or not it is considered an irritant. Products of identical chemical composition can not have mutually exclusive properties. One skilled in the art would not include a solid particulate that is an irritant to the skin regardless of its ability to act as a lubricant or preservative. This also reads on all irritants that are irritable to the skin. The claim reads on a method to treat diaper rash with a composition comprising a solid particulate. One skilled in the art would not add any solid particulate because all solid particulates would benefit a diaper rash and "provide a moisture barrier over the skin treatment area."

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617